



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2002.001 WO		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP 03/00514	International filing date (day/month/year) 15.01.2003	Priority date (day/month/year) 16.01.2002	
International Patent Classification (IPC) or both national classification and IPC A61K9/22			
Applicant AKZO NOBEL N.V. et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 14.08.2003		Date of completion of this report 17.02.2004	
Name and mailing address of the International preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Rodriguez-Palmero, M Telephone No. +49 89 2399-7871 	

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I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-17 as originally filed

Claims, Numbers

1-16 as originally filed

Drawings, Sheets

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-16
	No: Claims	-
Inventive step (IS)	Yes: Claims	-
	No: Claims	1-16
Industrial applicability (IA)	Yes: Claims	1-16
	No: Claims	-

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: POLYM. DEGRAD. STAB., 1994, 45(2): 249-57

Unless indicated, reference is made to the passages indicated in the international search report.

2. **Novelty (Art. 33(2) PCT)**

- 2.1 Present claims 1-13 concern a pharmaceutical composition comprising a polytartrate polymer and a pharmaceutically active material characterised in that the composition is capable of releasing the pharmaceutically active material in a pulsatile manner and is obtainable by forming the tablet with a compression force between 10 and 65 kN/cm². Claims 14-16 concern the process of preparing such a composition.

- 2.2 None of the documents cited in the search report disclose a pharmaceutical composition comprising a polytartrate polymer and at least one pharmaceutically active material obtained by forming the tablet with a compression force between 10 and 65 kN/cm², nor the process for its preparation. Therefore, the subject-matter of present claims 1-16 is considered novel in the light of the prior art documents cited in the search report.

3. **Inventive Step (Art. 33(3) PCT)**

- 3.1 D1 discloses tablets comprising polyalkylene tartrates and a pharmaceutically active material. Although D1 is silent about the compression force used for the preparation of the tablets, a compression force of about 10-65 kN/cm², as mentioned in independent claims 1 and 14 of the present application, is standard in the preparation of tablets. Therefore, the person skilled in the art would choose a compression force falling into such a range to make the tablets described in D1.

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- 3.2 Moreover, the present application fails to show that the compression force mentioned in claims 1 and 14, which is the feature that distinguishes present claims from D1, is responsible for the effect obtained (pulsatile release), i.e., that the use of another compression force does not result in a pulsatile release of the active substance.
- 3.3 Dependent claims 2-13 and 15,16 merely concern embodiments which come within the scope of the customary practice followed by persons skilled in the art and do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step.
- 3.4 Therefore, claims 1-16 of the present application cannot be considered inventive in the light of D1.
4. **Industrial applicability (Art. 33(4) PCT)**

Present claims 1-16 are susceptible of industrial application and thus do not contravene Art. 33(4) PCT.